BreakOut 3
Genomic Biomarkers in Regulatory Decision-Marking

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Some Questions

- What are the major concerns around proving 'clinical relevance' / 'clinical utility'
  - First we need to define clinical utility
- How should we put in context PGX data to other known clinical variables like age, sex etc?
- Factor in number needed to test in order to identify a 'targeted' patient?

PGX in Context of other Variables

- Should FDA / Sponsor assess what testing could be done instead of a PGX test?
  - What variables ‘co-localize with’ PGX test
- What is the alternative to PGX regarding management of safety /efficacy?
  - Is AE well managed ‘well’ anyway with current practice?
  - Is there a good non-PGX strategy?

Incremental use of Pharmacogenomic data in label

- What are the ‘natural increments’?
- No data in label?
- Data only w/o guidance on use?
- Data with instructions on possible consequences of test?
  - Optional PGX?
- Data with clear instructions on use of test
  - Required PGX

Issues of Third Parties and PGX Data

- 3rd party in academia
- 3rd parties in DX Industry
- What is the appropriate forum / pathway for dealing with 3rd party data?
  - How was this done in Irinotecan?
  - Is there other experiences that are case studies?

Label Information

- Where are possibly appropriate parts of the label for PGX data?
- Agency is considering new types of labels
- What kinds?
- What label changes would be appropriate to handle genomic biomarker data?